This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No. 875299

Project acronym: UNICOM
Project full title: Up-scaling the global univocal identification of medicines in the context of Digital Single Market strategy
Call identifier: H2020-SC1-DTH-2019

WP7 eHDSI cross-border / national eHealth services piloting

D7.2: Proof of Concept demonstrator report

Version:	1.0
Status:	Final
Dissemination Level[1]:	PU
Due date of deliverable:	30/11/2022
Actual submission date:	25/01/2023
Work Package:	WP7: eHDSI cross-border / national eHealth services piloting
Lead partner for this deliverable:	ARIA
Partner(s) contributing:	SPMS, SAS, IHE, HL7, INDRA, KELA, HZZO, INFARMED, REGLOMB, DWIZ, ELGA, IEDOH
Deliverable type[2]:	R

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[1] Dissemination level: PU: Public; CO: Confidential, only for members of the consortium (including the Commission Services); EU-RES: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); EU-CON: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/EC)

[2] Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent fillings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

Revision history

Version	Date	Changes made	Author(s)
0.1	30/08/2022	First initial draft: document structure	Angela Ferrara (ARIA)
0.2	28/10/2022	Second draft	Angela Ferrara Marcello Melgara (ARIA)
0.3	28/11/2022	Third draft	Marcello Melgara, Angela Ferrara, Isabella Dario, Luca Garbarino (ARIA)
0.4	16/12/2022	Fourth draft	Marcello Melgara, Angela Ferrara, Isabella Dario, Luca Garbarino (ARIA)
0.5	28/12/2022	Fifth draft, ready for review	Marcello Melgara, Angela Ferrara, Isabella Dario, Luca Garbarino (ARIA)
1.0	25/01/2023	Final version	Marcello Melgara, Angela Ferrara, Isabella Dario, Luca Garbarino (ARIA)

Deliverable abstract

Deliverable 7.2 (D7.2) defines the overall rules and criteria for running the piloting and assessing readiness for participation in the CEF eHDSI eP/eD. UNICOM WP5 and WP7 have been working closely with eHDSI communities, such as the eHDSI ePrescription Cluster, the Semantic Task Force, and the Requirement Specifications Group, to submit a Change Proposal for Wave 6 in September 2021, which includes new IDMP attributes to improve medication description and IDMP identifiers as optional elements. Since Wave 6 assets, released in June 2023, the eP/eD and PS may include the required IDMP attributes to describe medications, coded according to EMA-SPOR processes and compliant with eHDSI specifications, CDA Implementation Guides and ValueSets.
While cooperating with eHMSEG Communities to develop the Wave 6 assets and support their adoption, Task 7.2 demonstrate the integration of the Medicinal Product Database into their National Connector of the NCPeH A and B. This will enable the inclusion of data for cross-border dispensation in ePrescriptions for a specific set of selected Medicinal Products. The proof of concept will demonstrate how ePrescriptions, enhanced with IDMP data, can be used in the country of treatment to identify the Medicinal Products and provide suggestions to Member States implementing pilot services.
The Wave 6 Preparatory Pre-Production Testing has represented the formal start of the UNICOM eHealth Pilot with exchange of ePrescriptions/eDispensations and Patient Summaries among Italy, Cyprus, Greece and Ireland.

Key words: ISO IDMP; EMA; eHealth, ePrescription, Patient Summary,UNICOM, CDA Implementation Guide, ValueSets.

TABLE OF CONTENTS

Contents

List of Figures

List of Tables

List of Abbreviations

Abbreviation	Complete form
ADE	Adverse Drug Event
API	Active Pharmaceutical Ingredients
ATC	Anatomical Therapeutic Chemical Code
CEF	Connecting Europe Facility
CEN	European Committee for Standardization
eD	eDispensation
DSS	Decision Support System
EPF	European Patients' Forum
eHDSI	Health Digital Service Infrastructure
EHR	Electronic Health Record
EMA	European Medicines Agency
eP	ePrescription
epSOS	Smart Open Services for European Patients
EU	European Union
FDA	USA Federal Drug Agency
GDPR	General Data Protection Regulation
GP	General Practitioner
GS1	Global Standards One
HCPO	Healthcare Provider Organisation
HDR	Hospital Discharge Report
HL7	Health Level Seven
HP	Health Professional
ICD-10	International Statistical Classification of Diseases and Related Health Problems, 10th revision
IDMP	Identification of Medicinal Products
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
LTF	Legal Task Force
MPD	Medicinal Product Dictionary
MS	Member State
MVC	Master Value Catalogue
NCA	National Competent Authority (for human medicines)
NCP	National Contact Point
NCPeH	National Contact Point eHealth
NIA	National Identification Authority
Ophelia	OPtimising HEalth LIterAcy
OTC	Over the Counter
PhP	Pharmaceutical Product
PhPID	Pharmaceutical Product identifier

PS	Patient Summary
SDO	Standards Developing Organisation
SPOR	Substance, Product, Organisation and Referential
SubID	Identification of the (active) substance
TBD	To be done
UNICOM	Up-scaling the global univocal identification of medicines
WP	Work Package
WHO	World Health Organisation

1 Executive summary

The development of the UNICOM project aims to support the implementation of several use cases including the development of Identification of Medicinal Products (IDMP) as a global and univocal identification of medicines for cross-border ePrescription and eDispensation.
IDMP is a set of five different ISO standard specifications used to identify medicinal products. It defines the data elements and structures for the unique identification and exchange of medicinal products information. This approach to medicine identification aims to ensure better safety to the patients at national or cross-border levels.
The task will involve at least two Member States integrating the Medicinal Product Database into their National Connector of the NCPeH of the Country of Affiliation (Country A) and receiving IDMP enriched ePrescription / Patient Summary as Country of Treatment Country B). This will enable the inclusion of data for cross-border dispensation in ePrescriptions for a specific set of selected Medicinal Products. The proof of concept will demonstrate how ePrescriptions, enhanced with IDMP data, can be used in the country of treatment to identify the Medicinal Products, and provide suggestions to Member States implementing pilot services.
The Wave 6 Preparatory Pre-Production Testing has represented the formal start of the UNICOM eHealth Pilot with exchange of ePrescriptions/eDispensations and Patient Summaries among Italy, Cyprus, Greece and Ireland.

2 Introduction

2.1 Background

The healthcare industry involves a vast amount of complex information that needs to be gathered and shared among different healthcare settings to provide patient-centered care. Inadequate identification of medicines can hinder the safe delivery of cross-border healthcare.

To address this issue, the eHealth Digital Service Infrastructure (eHDSI) was established to manage the deployment and operation of services for cross-border health data exchange through the Connecting Europe Facility (CEF). eHDSI sets up and deploys core and generic services, such as Patient Summary (PS) and ePrescription (eP), for data exchange at the country and EU level, enabling the provision of Cross-Border eHealth Information Services (CBeHIS).

Additionally, the EU has launched the UNICOM project to define the rules and criteria for piloting and assessing the readiness of member states to participate.

More details about the background and the UNICOM project can be found in the deliverable *7.1 - Define the piloting strategy.*

2.2 Introduction to D7.2

This task, in conjunction with WP9, will involve at least two Member States integrating the Medicinal Product Database into their National Connector of the NCPeH of the Country of Affiliation (Country A) and receiving IDMP enriched ePrescription / Patient Summary as Country of Treatment Country B). This will enable the inclusion of data for cross-border dispensation in ePrescriptions for a specific set of selected Medicinal Products. The proof of concept will demonstrate how ePrescriptions, enhanced with IDMP data, can be used in the country of treatment to identify the Medicinal Product and provide suggestions to Member States implementing pilot services.

2.3 Scope of the document

The objective of this document is that of defining the overall rules of testing and describing the pre - production test conducted by Member States with a focus on the Italian approach.
In order to pursue the aforementioned goal, the present deliverable is structured in the following chapters:

- Chapter 1, presenting an executive summary;
- Chapter 2, introducing the UNICOM project and the Deliverable's background;
- Chapter 3, which describes the Wave 6 Change Proposals related to medicinal products and semantic and operative the assets upgrade;
- Chapter 4, providing an overview of the Pilot Product List with description of pre-production data and test;
- Chapter 5, describing the Italian implementation of Wave 6 assets and collaboration with UNICOM, Sogei and AIFA;
- Chapter 6, describe the performed tests among Italy, Cyprus, Greece and Ireland, which represent the formal start of UNCOM eHealth Pilot.
- Chapter 7 which presents conclusions and future steps;
- Chapter 8 – Annex, including eHDSI Concepts and Definitions, the eHDSI Change Proposal Management procedures and AIFA database analysis.

3 eHDSI Wave 6 Change Proposals to enhance ePrescription & Patient Summary

3.1 eHDSI Change Management process

For Wave 6, new Change Proposals were introduced. UNICOM co-operated with eHMSEG Communities, EC DG Santé Solution Providers, and Semantic Task Force to support the preparation of the Change Proposals related to the Medicinal Products and the alignment of eHDSI assets to Wave 6 specifications.

The procedure describing the Change Proposal Management used within the eHDSI framework, and in particular its workflow, can be read below, in Chapter 8 Annex Section. Its objective is to “assess and approve the integration of the change requests which can impact the policy, technical and/or operational activities of eHDSI”. It applies to requirements, specifications and frameworks and can have policy, operational or technical impact on eHDSI activities. The actors involved in the process are the requester, the eHDSI change manager, the eHDSI Solution Provider, the eHDSI Policy Owner and Co-owner, the e-Health Operational Management Board (eHOMB) (which oversees the provision of service and) and the stakeholders, including eHMSEG, the Communities and the Standards Development Organizations.

3.2 eHDSI Change proposals for Wave 6, related to medicinal products

The present section provides the list, title and description of the Change proposals for Wave 6, related to medicinal products, which are the following:

- CP-061, which comprises a collection of independent CDA Implementation Guide improvements, such as Change Cardinality of the eHDSI Allergy And Intolerance Concern, Change cardinality of hl7:entryRelationship that links to an observation within the Allergies and Intolerance concern, Fix code element definition in eHDSI Problem Status Observation, Remove negationInd and replace by the use of statusCode in eHDSI Immunization, Wrong determinerCode used for epsos:containerPackagedMedicine in eHDSI Material and various more;
- CP-062, focusing on Medication Information representation improvements through splitting eHDSI Manufactured Product template between PS and ePeD, to allow more flexibility to manage the specific requirements of the two use cases;
- CP-063, including five Improvements to medication information representation through the representation of the medicinal product complex packaging;
- CP-066, regarding the preparation of Business Requirements for the ISO IDMP Adoption by eHDSI. This CP has allowed the inclusion of EMA SMS substances code system and EDQM Quantity Unit, for the dose of presentation;
- CP-068, which concerns the extension of the Value Set for Timing Events in order to include in the HL7 v3-TimingEvent code list some missing codes of events which are frequently used in dosage information in many countries, i.e. Morning, Noon, Evening and Night;
- CP-070, concerning the update of the Value Sets in the MVC based on the newest versions of ICD-10 and Common UCUM Units;
- CP-071, related to the Automatic update of the Value Sets in the MVC based on ATC Classification, EDQM Standards Terms, EMA SMS Substance data, and ORPHAnet nomenclature.

3.3 eHDSI sematic assets updated for Wave 6, related to medicinal products

3.3.1 Master Value Set Catalogue MVC 6.1.0 / 6.2.0

The Master Value Sets Catalogue (MVC) is intended for use by countries deploying CEF eHDSI services. It is an updated version of the MVC developed in previous projects (epSOS and EXPAND). It consists of terms used within certain sections of the eHDSI pivot documents, such as patient demographics or clinical problems, and is based on standardized code systems like ICD-10, SNOMED CT, ATC Classification, EMA SMS, EDQM Standard Terms, or UCUM.

3.3.1.1. Implementation

The implementation of MVC 6.2.0 is currently in progress.

3.3.1.2. Release

Several versions of the MVC have been released. A table with the previous releases for the different Waves is **attached. As reported in the previous chapter, a version 6.2.0 is being implemented and will be released at the end of January 2023.**

VERSION	DATE	STATUS	FROM	ENVIROMENT(s)
6.1.0 *Wave 6*	20 Jun 2022	Operation ready	eHealth DSI	Acceptance
5.2.0 *Wave 5*	27 Jan 2022	Operation ready (implementation of CP-048)	eHealth DSI	Production from 16 May 2022 Acceptance Training
4.4.0 *Wave 4*	02 May 2022	Operation ready (implementation of CP-048)	eHealth DSI	Production Acceptance Training

Table 1: table representing the latest MVC releases for releases 4, 5 and 6

3.3.1.3. Upgrade

The MVC is constantly being updated, which is why the value sets inside are also updated. Below is a table **with the details of the latest updates of the value sets released for release 6.1.0.**

VALUE SET	CHANGE	JUSTIFICAZION OF THE CHANGE
eHDSIDisplayLabel	Updated the content of the Value Set: • 31 new concepts are added • 1 code is updated to avoid duplication • 8 descriptions are updated for being in	CP-eHealthDSI-065: Align Patient Summary with PS Guidelines v3

	same format as other concepts	
eHDSISubstance	Updated the content of the Value Set based on official SMS Code System export available in SPOR portal: • 522 new concepts are added • 7 concepts are removed • 211 descriptions are updated • UPDATED on 29 Jun 2022: • 2 descriptions are updated due to names are more than 1000 chars which are not correct according CTS specification, so cannot be uploaded. Those names were changed by official synonyms from List of substances · IRIS (europa.eu).	Official SMS Code System export available in SPOR portal: SPOR Web UI (europa.eu)

Table 2: table representing the updates for the latest release of MVC 6.1.0 with the respective reasons for the updates.

Furthermore, in table 3 there are the value sets that will be **updated in the next 6.2.0 release.**

VALUE SET	CHANGE	JUSTIFICATION OF THE CHANGE
eHDSIActiveIngredient	Update the content of the Value Set to the latest release of the ATC Classification (January 2023): • 116 new concepts are added • 5 descriptions are updated 8 concepts will be removed	CP-eHealthDSI-071:Improve Automatic Update of the MVC
eHDSIDisplayLabel	Update the content of the Value Set: • 5 new concepts are added 1 description will be updated	Bugfixes based on feedback from MS: EHEALTH-9394 - Authenticate to see issue details

eHDSIDoseForm	Update the content of the Value Set based on EDQM Code System snapshot on 2023-01-03: • 8 new concepts will be added 2 concepts will be removed	CP-eHealthDSI-071:Improve Automatic Update of the MVC
eHDSIPackage	Update the content of the Value Set based on EDQM Code System snapshot on 2023-01-03: 1 new concept will be added	CP-eHealthDSI-071:Improve Automatic Update of the MVC
eHDSIQuantityUnit	No changes on concept level, version of code system will be updated only based on EDQM Code System snapshot on 2023-01-03	CP-eHealthDSI-071:Improve Automatic Update of the MVC
eHDSIRouteofAdministration	No changes on concept level, version of code system will be updated only based on EDQM Code System snapshot on 2023-01-03	CP-eHealthDSI-071:Improve Automatic Update of the MVC
eHDSISubstance	Update the content of the Value Set based on official SMS Substances list export available in SPOR portal on 2023-01-03 • 1892 new concepts are added • 1242 concepts are removed 1546 descriptions will be updated	CP-eHealthDSI-071: Improve Automatic Update of the MVC

Table 3: table representing the updates for the future release of MVC 6.2.0 with the respective reasons for the updates.

3.3.2 Art Décor Implementation Guide 6.4.0

Art Décor Implementation Guide is the formal specification of the structure, the syntax and the semantic of the HL7 CDA documents exchanged in eHDSI.

Version 6.4.0 is a hotfix release for Wave 6 that addresses an issue that occurred when validating CDA documents against new XML schema definitions that include HL7 ePharmacy extensions and the Gazelle CDA Model Based Validator based on CDA IG v6.2.0 release. The latest release can be accessed through the following link: https://art-decor.ehdsi.eu/publication/epSOS/

The ART-DECOR Release and Archiving Manager (ADRAM) manages the release

publication and archiving of the project. A publication in ART-DECOR usually includes the following items derived from a DECOR project:

- An **HTML online extract** that serves as a "freeze" of the current specifications in the DECOR project. It includes project and version information, scenarios and transactions, value sets, templates, issues and a summary of the compilation process. The HTML is published on a specific website known as the "Publication location" and can be downloaded as a HTML Package that can also be used offline.
- A **Schematron Runtime Environment** containing the generated ISO schematrons from the templates, along with all other necessary items like value sets and pointers back from error messages to the published specification (as per the "see" instructions in the generated schematron).
- A generic or customized **PDF Publication** that can be downloaded upon request, containing all desired artefacts rendered in an appropriate form.

The Art Décor Implementation Guide version 6.5.0 is planned for January 2023.

3.3.3 OpenNCP Semantic Components

The OpenNCP is re reference implementation of the NCPeH, provided by EC DG Santé Solution Provider, developed in cooperation with the MS working in the eHMSEG Technical Group.

The OpenNCP 6.1.0 is the *MyHealth@EU Wave 6* Initial release including the implementation of the Wave 6 Change Proposals. This version is planned to be used by the Member States as preparation for the eHDSI Preparatory Test event for Wave 6 from October 2022 for their National implementation of the Wave 6 Change Proposals.

Wave 6 introduced changes in semantic assets that have been reported in the tables below and mapped according to the releases. In particular, the first table contains the MVCs considered essential for the pharmacological components and have been implemented by indicating an x where changes to the MVCs have been introduced.

The second table instead represents the semantic architectural assets.

A significant change performed in the HL7 CDA for ePrescription/eDispensation and Patient Sumary for Wave 6 is the adoption of HL7 ePharmacy Profile for Medicinal Products, in spite of the old proprietary epSOS specifications: this is really relevant evolution towards the adoption of International Standards.

First Wave 6 asset release was in June 2022, next will be in January 2023.

Asset	WAVE 6
Implementation guide	*6.5.0*
Central terminology server	*2.1.3*
OpenNCP	*6.2.0*
Configuration-manager	
e-sens-non-repudiation	
Security-manager	
Audit-manager	
Data-model	
Assertion-validator	
cda-display-tool	xsltransformer tsam-exporter
Default-policy-manager	
Trc-sts	
Trc-sts-client	
Tsam	

Tsam-sync	
Transformation-manager	
eadc	
Consent-manager	
Protocol-terminators	openncp-interface openncp-client-connector openncp-xdr-ws-client openncp-xdr-ws-server-impl openncp-nc-mock-it openncp-ncp-pt-utils openncp-ws-server
openatna	
Openncp-common-components	
openstork	
Openncp-gateway	

Table 4: table identifying the technology assets changes for the respective versions.

3.3.4 CDA Display Tool reference implementation

The CDA Display Tool is a component provider by EC DG Santé Solution provider as reference implementation of the application to display the HL7 CDA documents in the Portal at the Point of Care in the Country of Treatment.

For Wave 6, WP7 supported solution providers in the development and alignment of the CDA tool, to display, among all, the IDMP enriched eP and PS, and the complex packagings.

In particular, changes have been made to the tool to align the ePrescription and PS use cases for a better visualization of the defined fields in Wave 6.

For the ePrescription the substance and the corresponding ATC code are displayed in the title of a surrounding block. The block consists of three major parts:

- Medicinal product, with information about the prescribed medication, including substances.
- Prescription details, with information about the prescription itself.
- Packaging details, with information about the medication packaging.
- Dispensation details, with information about the dispensation.

An explanatory image of the CDA display tool is shown with the four blocks described above and one relating to package.
For more info, refer to the following link: *CDA Display Tool Guidelines - Wave 6 - My Health @ EU - eHealth Digital Service Infrastructure (eHDSI) - EC Extranet Wiki (europa.eu).*

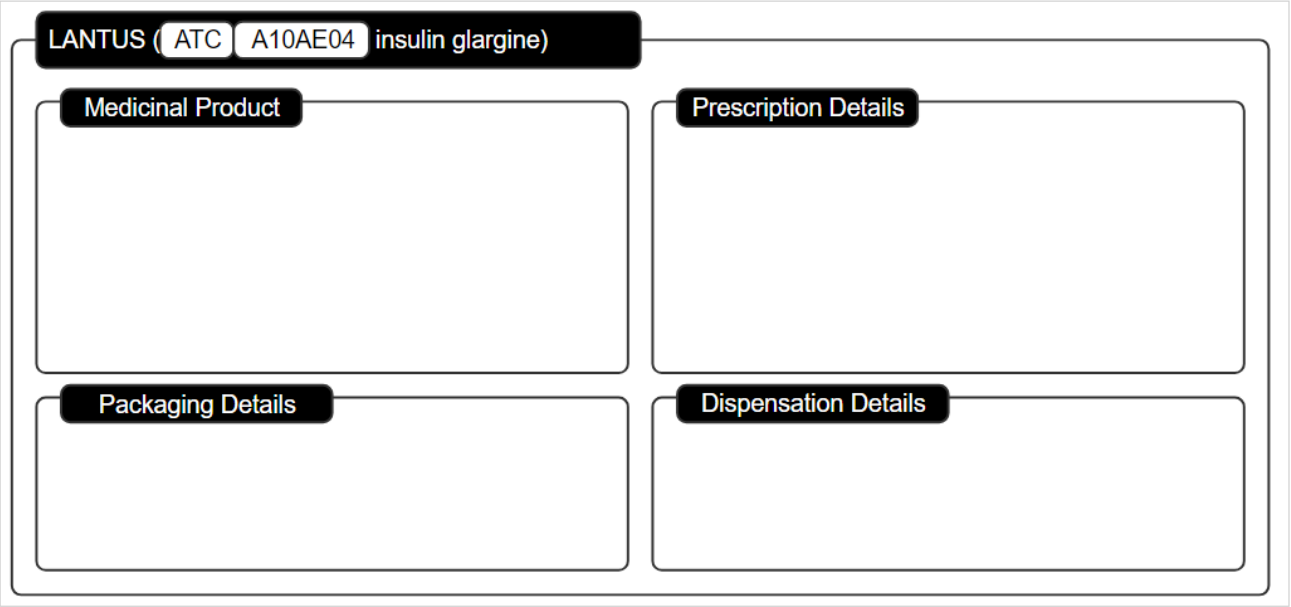

Figure 1:screen of the CDA display tool showing the implemented principal box for ePrescription.

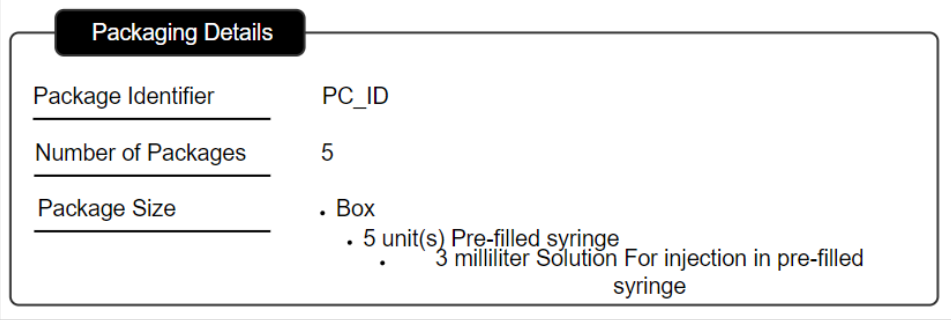

Figure 2: screen of the CDA display tool showing the implemented Packaging details box for ePrescription.

For the PS, in practice - by default – just few information like:

- Patient's Name
- Patient IDs
- Date of birth
- Gender
- Date of document creation
- Date of the last update

should be displayed above the document content, whose main structure is hereafter defined. All the other context information (author, contacts, guardian...) should not part of the basic representation and can be displayed only "on request".
For more info, refer to the following link: *PS Display Guideline - Wave 6 - My Health @ EU - eHealth Digital Service Infrastructure (eHDSI) - EC Extranet Wiki (europa.eu).*

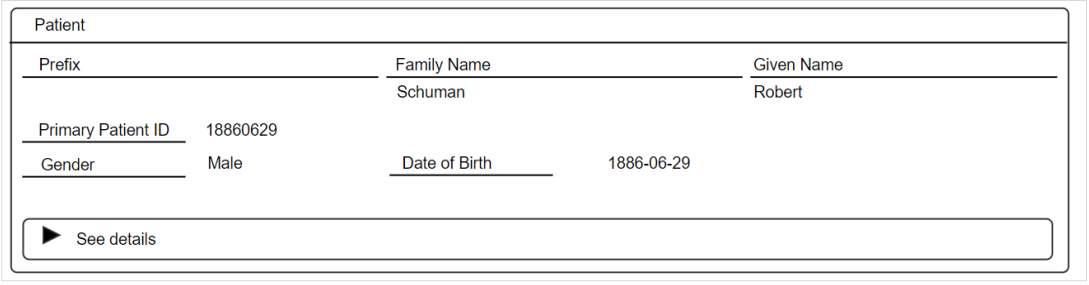

Figure 3: screen of the CDA display tool showing the implemented principal box for PS.

In the following tables is described how to display some “more complex” fields for the Wave 6.

3.3.4.1 Labels

EP

per unit [used to describe the unit “1”]
unit(s) [used to describe the unit “1”]
Every [used for period element]
for [used for phase.width]
at [used for phase.low]

Table 5: table describing how the attribute “label” is explicated for EP.

3.3.4.2 Strength

EP PS

The strength is expressed as a ratio. Hereafter is stated how it is expected to be shown in different use cases:

Numerator	Num. Unit	Denominator	Den. Unit	Display
50	mg	10	ml	50 [mg] / 10 [ml]
50	mg	1	ml	50 [mg] / 1 [ml]
50	mg	1	1	50 [mg] per unit
(Nullflavor) No information		[any value]		No information
50	mg	No information (Nullflavor)		50 [mg] / No information
50	mg	Missing value		50 [mg] /
Missing value		Missing value		/

Table 6: table describing how the attribute “strength” is explicated for EP and PS.

If no coded strength is available in the value and unit attributes of the numerator/denumerator, the values of the elements are taken.
For the ePrescription we make a difference between the strength:

- On substance level
- On ingredient level

3.3.4.3 Package Size

EP PS

The package size is a Physical Quantity value to be represented as follows.

Value	Unit	Display
50	mg	50 [mg]
50	1	50 unit(s)
(Nullflavor) No information		No information
Missing value		

Table 7: table describing how the attribute "Package size" is explicated for EP and PS.

3.3.4.4 Number of units per intake

EP PS

This information is expressed as a Physical Quantity range. Hereafter is specified how it is expected to be shown in different use cases:

Low	Low Unit	high	High Unit	Display	
				Low	High
50	mg	50	mg	50 mg	50 mg
50	1	50	1	50 unit(s)	50 unit(s)
50	mg	(Nullflavor) No information		50 mg	No information
(Nullflavor) No information		60	mg	No information	60 mg
50	mg	60	mg	50 mg	60 mg
50	mg	Missing		50 mg	
Missing		Missing			

Table 8: table describing how the attribute "Number of units per intake" is explicated for EP and PS.

3.3.4.5 Frequency of intake

EP PS

As described in the specification this info is provided through the second effectiveTime attribute of the substanceAdministration class.

4 Pilot Product List

4.1 Preparation testing data

The MyHealth@EU service requires test data to be input during testing events[1]. The test data are prepared by countries participating in the testing events and comes in two types: centrally defined Reference Test Data, which must be used during Pre-Production Test (PPT) events, (to demonstrate conformance to the eHDSI specifications), and National Representative Test Data, to highlight peculiarities of National implementation.

The MyHealth@EU service uses test data during testing events. Countries participating in the testing events have to prepare two types of test data, which are Reference Test Data and National Representative Test Data. Both types of test data are in the form of CDA level 1 (PDF embedded) and level 3 documents. The Reference Test Data is used to verify the system's semantic interoperability and serves as a common input known in advance by the participants. The National Representative Test Data is used to fully test the system and demonstrate readiness in a scenario that mirrors actual operation. This type of test data is the most relevant for testing eHDSI services during test events and is the only type that should be used during formal/upgrade test events.

These test data provide *known clinical content* that will be used as input to verify the semantic interoperable capability of the system; the Reference Test Data contains the clinical content of a Patient Summary/ePrescription document of a fictitious patient, of which all participants are cognizant. The goal of these Test Data is to provide a standardized input that all participants are aware of, resulting in predictable outputs. This allows for the validation of document processing, including difficult to describe data such as medicinal products.

This type of test data is only intended for use during Pre-Production Test events for countries testing the Patient Summary service. It provides countries with the opportunity to show that their implementation is correct, but to fully test the system and demonstrate readiness in a realistic scenario, National Representative Test Data is the appropriate data to use.

The Solution Provider has created a sample Reference Test Data description for use during testing events. As a result, participating countries are required to prepare documents that simulate a clinical case and participate in the exercise using a Friendly A document with the same clinical content, as well as XML files that comply with CDA Level 1 (with PDF/A embedded) and CDA Level 3 (structured body with narrative blocks and encoded entries) in 3 versions (complete, invalid and null flavoured). The Reference test clinical case, although fictional, aims to be as realistic as possible by including content for various clinical sections (e.g. pregnancy, medical implants, allergies, past surgeries, past and current problems, etc.). Additionally, the selection of medication is intended to be realistic and reflective of real-life treatment options, even if it may not be appropriate for a pregnant woman, in order to provide examples of both easily describable and more difficult to describe medicinal products.

National Representative Test Data are documents that simulate the typical data generated by the national infrastructure in order to test the services in the most realistic scenario possible. Participating countries in the testing events need to prepare their own documents that mimic the data that is available in their national infrastructure or use real data that is completely anonymized to protect patient privacy. No real person identifiers should be used during the testing. The goal is to provide documents with the same type of content (structure and coded data) as they would be able to exchange during the operation of the service. These documents

[1] All information and definitions related to the eHDSI Testing Strategy can be found here: https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/3.+eHDSI+Test+Services and here: https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSIEHMSEG/Improvement+of+the+Test+Framework

will be provided as XML files that comply with CDA Level 1 (with PDF/A embedded) and CDA Level 3 (structured body with narrative blocks and encoded entries). Optionally, English textual translations of the content are provided to assist health professionals in other countries during the validation of the service in the functional end-to-end testing.

National Representative Test Data is the most appropriate type of test data to use during Test Events and is the only type that should be used during Formal/Upgrade Test Events. This is because while Reference Test Data creates a controlled fixed scenario with known inputs, National Representative Test Data provide realistic examples that allow for testing the service in a scenario that is closer to the one in operation. Furthermore, using National Representative Test Data is the best way to assess countries' readiness to provide accurate and meaningful documents.

Reference Test Data outlines the types of prescriptions that must be generated by every participating country in order to participate in testing. If a country is unable to generate a specific prescription type, it must document this exception. The specifications for Reference Test Data are available on the eHDSI Confluence. Countries are responsible for creating the necessary prescriptions in their test environments and reporting this information on Confluence, at least one week before the start of the testing period.

Id	ATC code and active ingredients	Strength and dose form	Package size and package type	Posology	Other features	Reason for inclusion in test
eP-C1	H05AA02, Teriparatide	20 mcg/dose, Solution for injection	28 doses, pre-filled pen	1 dose each 24 hours or 20 mcg each 24 hours	Valid for maximum time, permanent medication	Unit “dose” in strength and two options for posology indication

Table 9: table structure for Reference Test Data entities.

National Representative Test Data (NRTD) can be created by each country participating in testing as Country A. NRTD entries are additional prescriptions that are included in the test to check specific cases for the given Country A. These prescriptions must be obtained and examined by every Country B acting as a test partner. A maximum of 15 entries is allowed for this list. The list must be made available on eHDSI Confluence one week before the start of a testing period. The structure of the list A is as follows (with one example entry provided). Entries from all countries are published in a single table on eHDSI Confluence.

Id	Requesting country	Prescription name	Prescription specification	Reason for inclusion in test	Critical parts for examination
eP-SA-FI1	FI	DAPSON	ATC: J04BA02 Dapsone, 50 mg/tablet, 100 tablets in a plastic jar.	Drug with a temporary special permit	Active ingredient and ATC code.

Table 10: table structure for National Representative Test Data entities.

Each country participating in testing as Country B may specify additional prescriptions that it needs to be able to examine for specific reasons. These prescriptions must be generated and made available by every Country A acting as a test partner. If a prescription cannot be provided

by a Country A due to a country-specific issue, the Country A must document this exception and provide a justified reason for it. A maximum of 10 entries is allowed for this country-specific list. The list must be published by Country B one month before the start of a testing period. The specified prescriptions must be prepared by test partners one week before testing. The structure of the list B is as follows (with one example entry provided).

4.2 Ongoing activities to prepare testing Data with NCAs

For the creation of the data described in chapter 4.1 WP7 collaborated with the semantic task force and eP cluster.
A table with the critical Data for each member states was created and it can be found at the following link: *Critical Test Data - My Health @ EU - eHealth Digital Service Infrastructure (eHDSI) - EC Extranet Wiki (europa.eu)*
In the table, for each drug is described:

- Id
- ATC code and active ingredient
- Strength and dose form
- Package size and type
- Posology
- Other features (if applicable)
- Reason for inclusion in test

It has to be noted that these attributes coincide with the Minimal Attribute List defined in UNICOM WP5.

For this table also contains a column for each member state where it is indicated whether the drug is present in that state and therefore the description and the patient ID and ePrescription code if it was used for the tests.

4.3 Pre- production test

The pre-production test consists of two moments of assessment for the specifications, a first one in a more informal session and another in a final and formal setting.

Informal test session

The first kind of test, also called Preparatory Pre-Production Testing, that is carried out is structured among the set of Test Events defined by the *eHDSI Test Framework* to assess the readiness and conformity of the NCPeH technical gateway of the deploying countries with the eHDSI Specifications. It represents a first moment of assessment of the degree to which the implemented solutions are compliant with the specifications. This is useful to tackle and resolve potential shortcomings before the formal test session.

To fulfill the testing objectives, NCPeH should ensure that the testing environment for the connection with the National Infrastructure replicates the production environment. To do so, National Representative Test Data should be used to realistically reflect what the documents would contain in real operation once the solution is deployed, both in terms of documents' content as well as clinical scenarios.

As for the actual features of the test, the first informal session occurs in a 5 weeklong period and is carried out online before the formal testing session. Nonetheless, it is an optional but strongly suggested stage of the preproduction testing to anticipate potential shortcoming that would be then displayed directly in the formal testing.

The results of the test are given to the deploying countries and illustrate the performance of the infrastructure in terms of connectivity and conformance testing. These reports can be made available also to other participating countries that can identify issues that can be optionally

managed by the partner countries.

Formal/Upgrade Pre-Production Testing (Formal/Upgrade-PPT)

This is the second moment of assessment to formally demonstrate the compliance of the infrastructure with the eHDSI specifications. It requires deploying countries to complete Conformance and Functional tests with at least 3 partner countries that follow a set of criteria:

- a partner from whom you can consume or provide services to;
- at least 2 partners in routine operations: these partners represent solid experience and stable/mature solutions;
- at least 1 partner launching new services: newcomers bring additional challenges and require additional effort from test partners.

Similarly to the informal pre-production test, it is a 5 week long online session that occurs once a year after the preparatory test session. Moreover, the NCPeH is responsible to ensure that the tested technical environment mimics to the maximum possible extent the production environment and uses National Representatives Test Data. Nonetheless, the results of the test are given to the deploying countries in the form of a set of reports that highlight findings and observations, and partners can report issues for each other regarding the functional part.

Differently from the informal session, it is mandatory for all NCPeH launching new services as well as for countries in operation that must update new specifications (eg. Case of a NCPeH that started routine operations with Wave 3 specification and now needs to upgrade to Wave 4 specs). In fact, the outcome of the Formal/Upgrade PPT the Deploying Country in its form of Outcome Summary Test Report is necessary to obtain:

- the eHMSEG Decision to be authorized to start Production Environment Tests (eHDSI Procedure 3);
- the eHN Decision to start the NCPeH new service Routine Operations (eHDSI Procedure 4);
- the eHMSEG Decision to start the NCPeH new exchange for the service already in Routine Operations (eHDSI Procedure 5);
- the eHMSEG Decision to continue the NCPeH Routine Operations after the annual Upgrade (eHDSI Procedure 6).

5 The Italian implementation for eHDSI Wave 6 Preparatory Pre-Production Testing

5.1 The Italian National Connector

The Italian NCPeH is developed by the consortium acting within MyHealth@EU, led by the Italian Ministry of Health, the Italian Ministry of Finance with Sogei, its in house ICT Company, AgID, Lombardy Region with ARIA S.p.A.. Emilia Romagna Region with Lepida, Veneto Region with Azienza 0 and Arsenal. Recently Friuli Venezia Giulia and Calabria Regions joined in the new NCPeH Plus consortium.

The Italian architecture of country A is made up of national connectors to which the National Infrastructure (i.e. the Italian EHR (FSE) for clinical documents and the ePrescription System (the database of electronic prescriptions), the citizens' registry are connected.
The input it receives is a national transcript layout of the Italian ePrescription, that contains the Market Registration Number (AIC) or the equivalence group of the prescribed medicinal product.
To make it compliant with the eHDSI cross-border specifications, it has been required the creation of a drug database within the Italian national connector which has the AIC or Equivalence Group as pointer to the related medicinal product set of attributes. Clearly each record of this database contains all the structured and codified information of that drug.
This approach was also followed in epSOS: in that pilot project, the Lombardy Region had requested a special supply from the drug database provider in which the attributes required by epSOS were added to the drug database.

The same approach was followed in MyHealth@EU.

Sogei developed the drug database within the national connector, and for Wave 6, the Italian UNICOM team helped fill them with IDMP compliant content.
Possibly a direct connection with the AIFA DB, the Italian NCA, is envisaged.
The country connector generates the eHDSI compliant ePrescription CDA Level 3.
The same approach is applied for medication summary in PS.

As far as eDispensation is concerned, however, the country connector does not convert it into the Italian format: it just sends it to the Italian ePrescription System, that stores it, by the electronic prescription referred to, and mark that eP as dispensed.
The drug dispensed abroad is not remapped to a corresponding national one, for traceability and pharmacovigilance purposes.

The figure below shows the architectural scheme of the Italian national connector within the Italian National Architecture as Country of Affiliation.

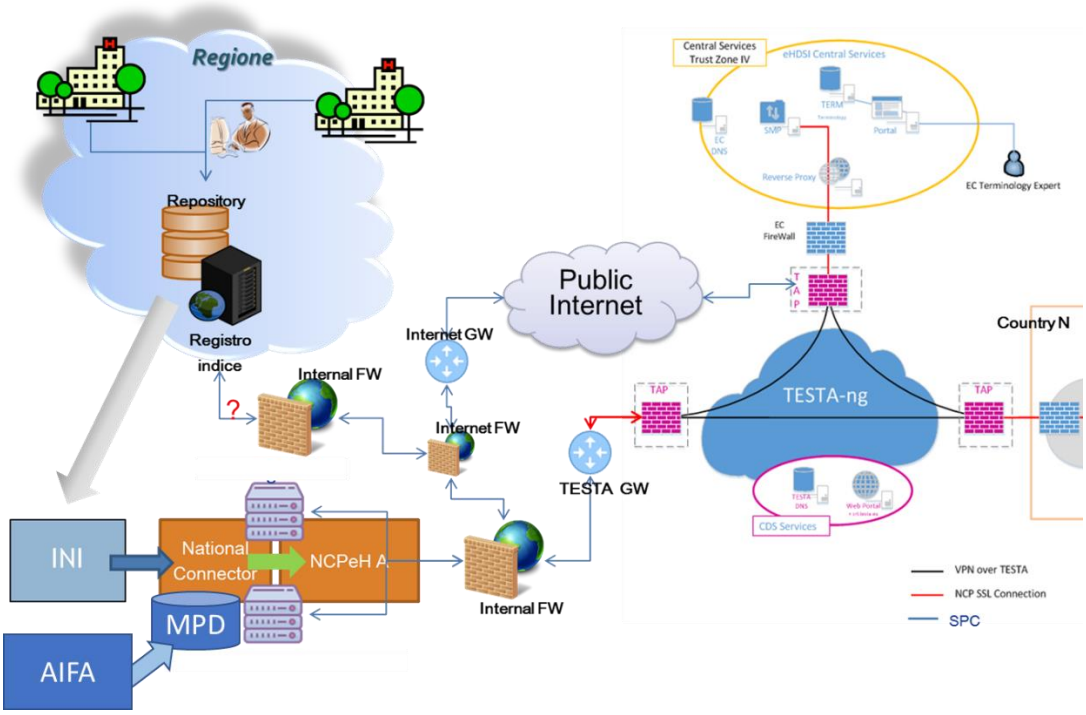

Figure 4: schema represent the Italian architecture of the national connector and the workflow with the interactions to entities.

5.2 Prepare testing Data with UNICOM, SOGEI and AIFA

A structured approach described below was used for the preparation of the test data.
It's started from a database downloaded on AIFA website and made available at followed link *Elenchi farmaci di classe A e H | Agenzia Italiana del Farmaco (aifa.gov.it)*, a database of only class A drugs since in Italy drugs are divided into A, H and C classes.
The coding work started from class A drugs.
Currently, the database contents are exported and made available as an excel file including about 10000 drugs and for each drug the presence of the follow attributes:

- Active ingredient
- Description Group
- AIC holder
- AIC code
- Equivalence Group Code

For more details about starting point file, please see the table in the Annex **Error! Reference s ource not found.**.

The 10.000 drugs were divided into groups based on the diversity and the complexity and for each group it was assigned a priority.
Five groups have been identified with five different priorities from 1 to 5 as follows:

- priority 1 solid drugs composed of only one active ingredient
- priority 2 solid drugs composed of two or more active ingredients
- priority 3 non-solid drugs and therefore solutions
- priority 4 is oxygen
- priority 5 complex drugs or those composed by several components.

The priority represents the order in which the drug groups were analyzed and coded.
Figure 5 shows the percentages of drugs present in each group, in particular it is possible to learn that most of the drugs are solid drugs with only one active ingredient.

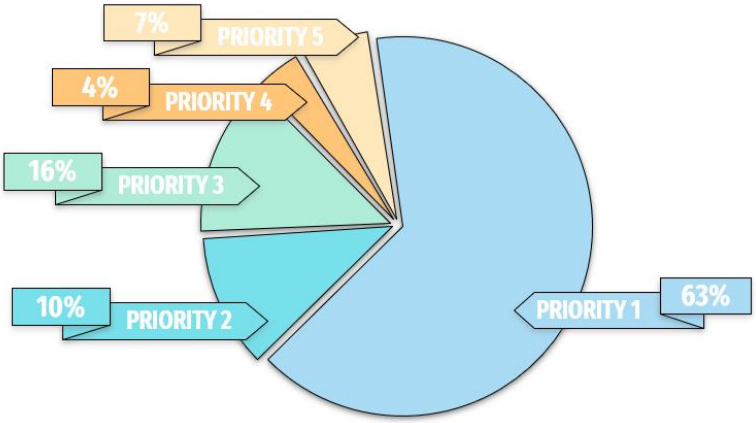

Figure 5: pie chart representing the subdivision of the 10,000 drugs into their respective priority groups with the relative percentage.

Starting from the priority 1 and subsequently 2, using the mentioned excel file, the “description” attribute was used and for each drug a structured excel file was created with coded fields.

Principio Attivo	Descrizione Gruppo	Denominazione e Confezione	Prezzo al pubblico €	Titolare AIC	Codice AIC	Codice Gruppo Equivalenza
Acamprosato	ACAMPROSATO 333MG 84 UNITA' USO ORALE	CAMPRAL*84 cpr riv gastrores 333 mg	33,77	BRUNO FARMACEUTICI SpA	034208013	H0A
Acarbosio	ACARBOSIO 100MG 40 UNITA' USO ORALE	ACARBOSIO*40 cpr 100 mg	5,63	TECNIMEDE SOC.TECNICO-MED.S.A.	039716182	H1A
Acarbosio	ACARBOSIO 100MG 40 UNITA' USO ORALE	ACARBOSIO*40 cpr 100 mg	5,63	DOC GENERICI Srl	044155024	H1A
Acarbosio	ACARBOSIO 100MG 40 UNITA' USO ORALE	ACARPHAGE*40 cpr 100 mg	5,63	MERCK SERONO SpA	038835144	H1A
Acarbosio	ACARBOSIO 100MG 40 UNITA' USO ORALE	GLUCOBAY*40 cpr 100 mg	8,04	BAYER SpA	026851016	H1A

Medicinal Product Name	Titolare AIC	(outer container)	ge 1 (outer container) (EDQ	Dose form (EDQM Co	Dose form (EDQM Label)	esentation 1 (I
ACIDO URSODESOSSICOLICO MYLAN GENERICS	MYLAN SpA	30009000	Box	10219000	Tablet	15054000
ACIDO URSODESOSSICOLICO ZENTIVA	ZENTIVA ITALIA Srl	30009000	Box	10210000	Capsule, hard	15012000
DEURSIL	CHEFIAPHARM ARZNEIMITTEL GMBH	30009000	Box	10210000	Capsule, hard	15012000
LITOFF	I.B.N. SAVIO Srl	30009000	Box	10219000	Tablet	15054000
LITURSOL	EG SpA	30009000	Box	10219000	Tablet	15054000
URDES	S.F. GROUP Srl	30009000	Box	10219000	Tablet	15054000
URSILON	I.B.I.GIOVANNI LORENZINI SpA	30009000	Box	12100	Capsule	15012000
URSOBIL	ABC FARMACEUTICI SpA	30009000	Box	10219000	Tablet	15054000
URSOFLOR	SO.SE.PHARM Srl	30009000	Box	12100	Capsule	15012000
URSOLISIN	MAGIS FARMACEUTICI Srl	30009000	Box	12100	Capsule	15012000
FRAURS	FRANCIA FARMAC.IND.FAR.BIO.Srl	30009000	Box	12100	Capsule	15012000
ACIDO URSODESOSSICOLICO	RATIOPHARM GMBH	30009000	Box	10226000	Prolonged-release tablet	15054000
ACIDO URSODESOSSICOLICO DOC GENERICI	DOC GENERICI Srl	30009000	Box	10217000	Modified-release capsule, hard	15012000

Figure 6: image showing the file used as a starting point and the final file generated with their respective structures.

The attributes chosen for encoding are those defined in the minimum attribute list, defined in UNICOM WP5, where the MVC 6.1.0 were used and therefore an EDQM encoding.

The file is structured as follows:

- For each row there is a coded drug
- For each column there are attributes defined by the minimum attribute list to be coded.
- If a drug contains more than one active ingredient or if the drug box contains several components, you have chosen to create multiple columns for the single coding.
- Once the structure was defined, then it’s moved on to defining an approach to implement the coding of each defined attribute.

In particular, for each drug, the "description and packaging" field present in the AIFA DB excel file was analysed, which is nothing more than the description on the packaging for each drug, and the coding fields were extracted.
An explanatory workflow of the analysis process and therefore of the implementation of the coding is reported.

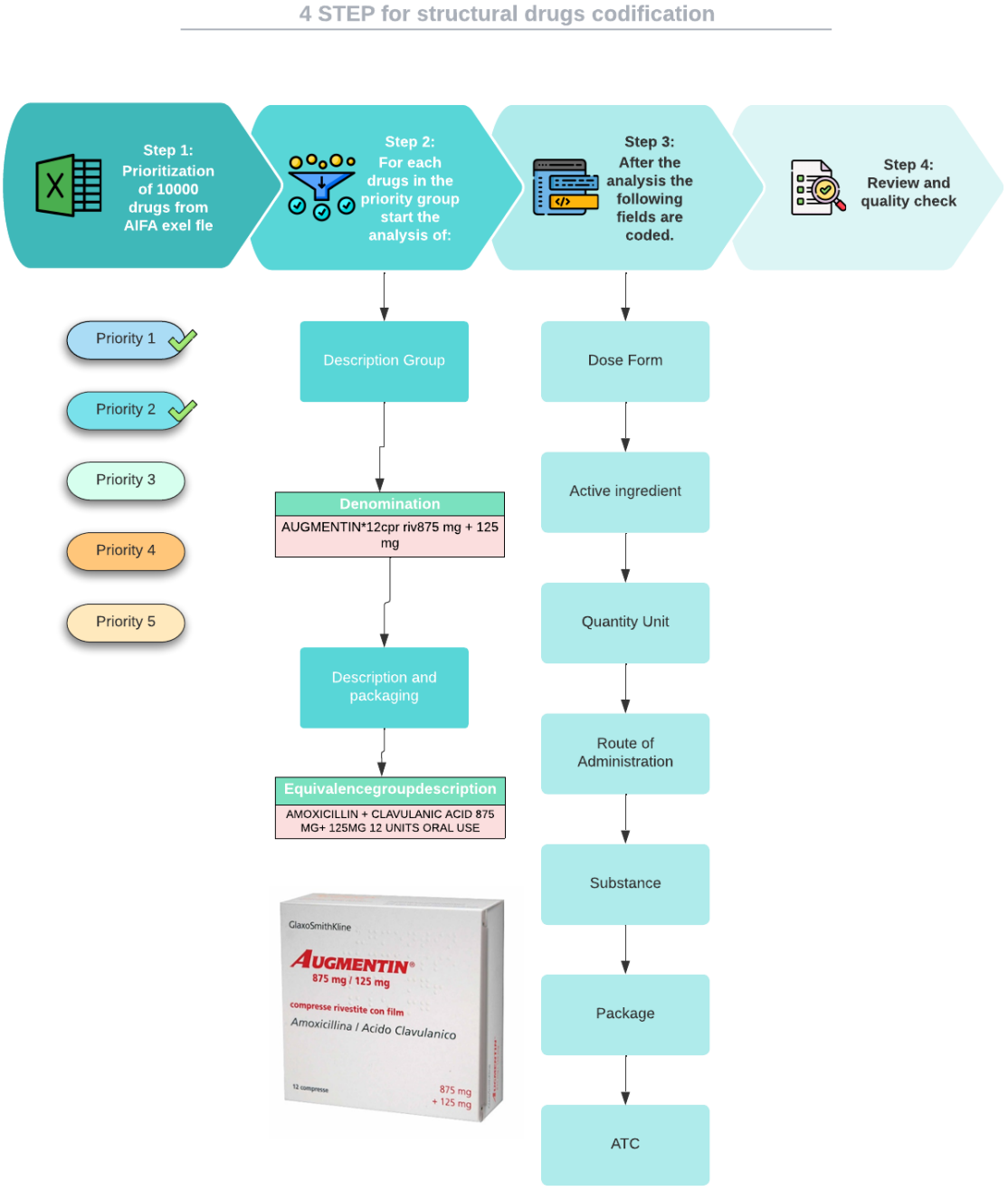

Figure 7: image describing the scheme and therefore the workflow followed to codify the Italian class A drugs.

As shown by the workflow and the figure 8 below, from the description of the drug on the box, the fields were broken up, identified and then coded, defining the attributes and using the MVC to report the respective EDQM codes of the attributes identified within the description. Following this approach, of the 10,000 drugs, approximately 7,000 drugs were coded and were added in UNICOM DB after review and a json transformation.

It is planned to complete the full coverage of the medicinal products, in co-operation with AIFA.

As for priority 4. Oxygen, it has to be agreed, within eHMSEG eP Cluster, if they will be included in the scope of MyHealth@EU eP services, being currently not considered. However the need for them was made evident during the COVID-19 pandemic crisis.

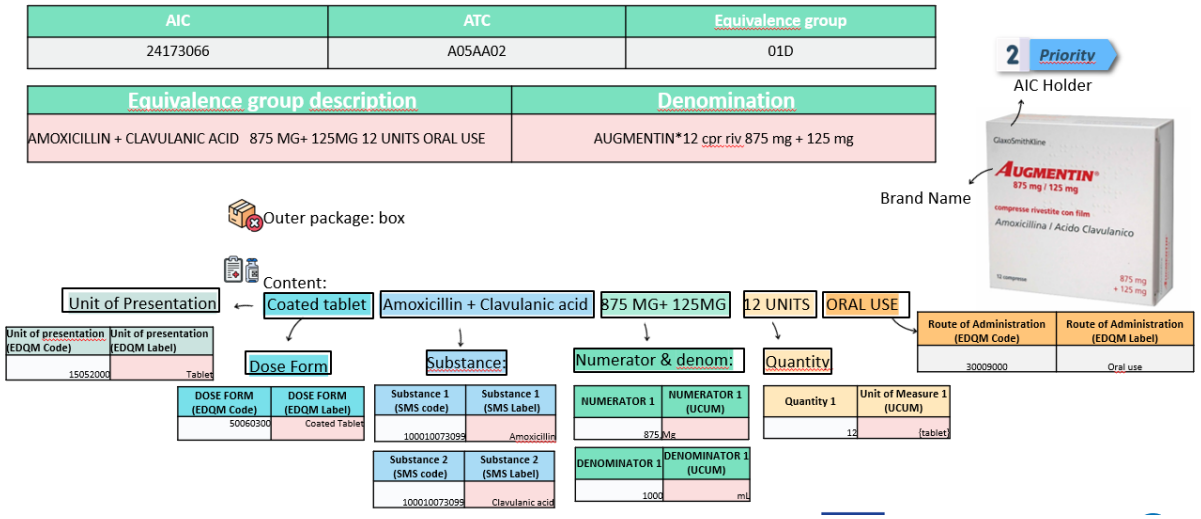

Figure 8: image describing the process started from box description followed to codify the Italian class A drugs

5.3 Wave 6 Preparatory Pre-Production Test

Following the same approached described in Section 5.2, all the drugs defined as critical test data for the UNICOM project have been codified.
At the following link it is possible to find the table including all the critical data identified for each member state: *Critical Test Data - My Health @ EU - eHealth Digital Service Infrastructure (eHDSI) - EC Extranet Wiki (europa.eu)* .

This coding and this approach were shared with Sogei and together we proceeded to the coding of only drugs with ATC code.
A table below shows with the identification of these critical defined and coded fields.

AIC	HOLDER AIC	DENOMINATION	DENOMINATION PACKAGE
021643010	ALFASIGMA SpA	ANDROKUR ALFASIGMA	10 mg, film-coated tablet, 100 tablets, blister
021643022	ALFASIGMA SpA	ANDROKUR ALFASIGMA	10 mg, film-coated tablet,100 tablets, blister
021643046	ALFASIGMA SpA	CARVEDILOLO DOC GENERICI	10 mg, film-coated tablet,100 tablets, blister
033484041	ANGELINI SpA.	TWICE	100 mg, prolonged-release tablet, 100 tablets, blister
035724121	SANOFI AVENTIS DEUTSCHL GMBH	LANTUS	100 U/ml, Solution for injection, 5 x 10 ml, vial
037741016	Doc Generici s.r.l.	ENAL-IDROCL DOC	20/12.5 mg, tablet, 98 tablets, blister
034213049	Laboratoire Innotech Int.	IDEOS	500 mg/10 mikrog (may be represented as 500 mg/800 IU), chewable tablet100 tablets, tablet container
043427071	Servier Italia S.p.A.	TRIVERAM	20/10/5 mg (atorvastatin / perindopril / amlodipine), film-coated tablet 400 tablets, tablet container

Table 11: table containing the drugs codified with Sogei.

For each of these drugs, the same approach was followed and the following fields were codified:

- ATC
- active ingredient
- active ingredient numerator quantity
- active ingredient numerator unit of measurement (ucum)
- quantity
- unit of measure (ucum)

- route of administration (edqm code)
- route of administration (edqm label)
- dose form (edqm code)
- dose form (edqm label)
- strength
- active ingredient denominator quantity
- active ingredient denominator unit of mesurement (ucum)
- dose quantity low
- dose quantity low unit
- dose quantity high
- dose quantity high unit
- multi-ingredient (flag)

The attributes mentioned above have been identified for the selected drugs. The multifactor field is a Boolean and it is good to specify that when a drug had more active ingredients, the field was implemented with true.
There will be more columns of the following attributes to identify the individual components.
The excel file is composed as follows:
For each row there is a coded drug
For each column there are attributes defined above.
If a drug contains more than one active ingredient or if the drug box contains several components, there are as many columns as there are active ingredients to describe the following fields:

- active ingredient
- active ingredient numerator quantity
- active ingredient numerator unit of measurement (ucum)
- active ingredient denominator quantity
- active ingredient denominator unit of measurement (ucum)
- ATC

5.4 Ongoing activities toward Wave 6 Formal Pre-Production Testing

From Wave 6 we started collaborating with AIFA to systematize the coding process.
In particular, the approach used for drug coding used in UNICOM was presented to the AIFA team and reasoning was started based on this approach.
In particular, a process of analysis of the AIFA internal DB was started to understand which attributes are already currently codified and therefore present in the internal DB.
For the attributes identified in UNICOM and therefore the minimum list of attributes, it has been seen that the AIFA database already contained most of these attributes. This made it possible to compare the sets of values used by coded account.
It emerged from the analyzes that the fields are encoded with the MVC and so same codes used by UNICOM, except for some fields where is present EMA RMS coding and not EDQM and for the substances where, however, AIFA declares in the future to also switch to EMA SMS coding while now maps substances with the EMA XEVMPD.
The purpose of this work, as already mentioned in chapter 5.1, is to collaborate with AIFA to integrate the AIFA drug database with the national connector.
We are also working with the semantic task force to create a code that transforms RMS into EDQM. This could make coding much easier, so it would allow us to use AIFA coding and transform it directly.
It is planned to directly import medicinal products coded attributes from AIFA DB into the National Connector Medicinal Product DB.

6 Formal start of UNICOM Pilot during the Wave 6 Preparatory Pre-Production Test

Taking advantage of the availability of the Italian implementation of the fully Wave 6 compliant ePrescription and Patient Summary services, during the Wave 6 Preparatory PPT sessions, in **November 2022**, Italy, acting as Country of Affiliation, sent IDMP enriched ePrescriptions and Patient Summaries to the following member states:

- Cyprus,
- Ireland,
- Greece.

Those states have recalled our drugs for ePrescription, and Patient Summary and sent the data for eDispensation back to Italy. In the table the drugs exchanged between the aforementioned countries and for their respective use cases (ePrescription and patient summery) were added.

The following table lists the performed exchanges.

Country	Drug	Use Case
Ireland	eP-C4 (C10BX11/atorvastatin, amlodipine and perindopril)	ePrescription
	eP-C8 (N02AA01 Morphine)	
	eP-C2 (A10AE04/Insulin glargine)	
	eP-C5 (A12AX Calcium)	
Cyprus	eP-C8 (narcotic)	ePrescription
	eP-C2 LANTUS INJ.SOL 100 IU/ML BTx10 PF PEN	
	eP-C5 IDEOS* 60 CPR MAST	
	eP-C12 EnaHexal Comp 20 mg/12.5 mg tablets 100 units	
Greece	eP-C4 TRIVERAM 20/10/5 MG/TAB	ePrescription
	eP-C8 ORAMORPH 20MG/ML	
	eP-C2 LANTUS OPTISET 100	
	eP-C5 IDEOS CHW.TAB (500MG+400IU)/TAB	
	eP-C12 RENITEC 20MG/TAB	
Cyprus Greece Ireland	EUTIROX*100MCG 50CPR	Patient Summary

Table 12: table containing the drugs used by Sogei for the pre-production test with the different countries.

The Gazelle Document Scrutiny tests and Workflow tests were positively passed, as it was for the end-to-end functional tests.

7 Conclusions and further actions

Deliverable D7.2, after a thorough analysis of the eHDSI architecture and components, addresses the process of defining the changes to be implemented in the eHDSI assets (the specifications, the Master Value Sets Catalogue and the Art Décor Implementation Guide) and the software resources (the OpenNCP semantic components and the CDA Display Tool portal, as a reference implementation of the NCPeH).

It has been presented how those core components were aligned to Wave 6 and how national semantic components including the National Connector might be aligned to Wave 6 specifications.

A possibility to be considered by Member States is to adopt an appropriate Database of Medicinal Products, such as the one developed in UNICOM T6.1, to decouple the cross-border services from the currently operational national services.

It has been presented the Italian approach used for the creation of a codified and integrated database within the national connector thanks to the collaboration of Sogei, which allowed the run of the Preparatory Pre-Production Testing.

The Wave 6 Preparatory Pre-Production Testing has represented the formal start of the UNICOM eHealth Pilot with exchange of ePrescriptions/eDispensation and Patient Summaries among Italy, Cyprus, Greece and Ireland.

The next step for Italy is to continue the activity with AIFA, the Italian NCA, to obtain directly from the AIFA database the coded attributes for the eHealth cross-border services.

Other Member States are progressing with these joint activities between the National eHealth authorities and the NCAs.

The first step we are all considering is obtain the IDMP Minimal Attribute encoded data elements and the Critical test data, to be able to start with the Pre-Production Testing, waiting for the formally certified Medicinal Product coded data to be allowed to enter in Routine Operation.

We are all aware that the strict co-operation EMA, MyHealth@EU governing bodies and Solution Provider, the NCAs and the National eHealth Authorities will be the key for successful and safe cross-border services.

8 Annex

8.1 Concepts and Definitions

This chapter intends to present the definition of the terms and the main concepts that are used on this document in order to ensure the correct understanding of the text. The source of all definitions used can be found in the annex and come from CEF eHDSI glossary.

Concept	Definition
Active substance/ Active ingredient/ Active pharmaceutical ingredient	Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.
Actors	► Actors may represent roles played by human users, external hardware, or other subjects. ► Actors do not necessarily represent specific physical entities but merely particular facets (i.e., "roles") of some entities that are relevant to the specification of its associated use cases. ► A single physical instance may play the role of several different actors and a given actor may be played by multiple different instances. ► Types of actors include: Users, database systems, clients and servers, cloud platforms, devices
Adverse Drug Event	A response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the restoration, correction or modification of physiological function.
Allergen	A usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction. Example of allergens: pollen, dust mites, animal dander, mould, medications, insect venoms and various foods.
Attribute	A property or a characteristic of an entity. eHDSI use: Identity Management Specification
Available prescriptions	The prescriptions that can be retrieved for the patient in the act of dispensing (at that specific or particular moment). This implicitly means that it is a time valid prescription.
Brand name or Name of the medicinal product	The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorization holder.
Business actor	Business Actors perform business processes or functions in an organisation. Business Actors are humans working in departments, and business units. Business Actors may be individuals or groups such as healthcare professionals.
Connecting Europe Facility eHealth Digital Service Infrastructure	The initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). eHDSI sets up and starts deploying the core and generic services, as defined in the CEF, for Patient Summary and ePrescription. EU financial mechanism (based on call for proposals) that was launched by November 2015 and used by MS to support CBeHIS provision (preparation, deployment and operation of NCPeH - meaning generic services in CEF).
Clinical Information System	Solutions of Primary Care Centres, General Practitioner's for documentation and Prescription.
Coding System	A scheme for representing concepts using (usually) short concept identifiers to denote the concepts that are members of the system; defines a set of unique concept codes. Examples of coding systems are ICD-9, LOINC and SNOMED.
Concept	Unit of knowledge constructed through combining characteristics.

Concept	Definition
Connecting Europe Facility	A key EU funding instrument supporting the development of high performing, sustainable and efficiently interconnected trans-European networks in the fields of transport, energy and digital services (telecom).
Dispensed Medicine	The medicine given to a patient as indicated in the prescription ordered by a prescriber.
Dispenser	Healthcare professional who provides the order of a prescription. The professional person must be authorized to do so.
Pharmaceutical Dose Form	The physical manifestation (“entity”) that contains the active and/or inactive ingredients that deliver a dose of the medicinal product. The key defining characteristics of the Dose Form can be the state of matter, delivery method, release characteristics and the administration site or route for which the product is formulated. A term for the physical characteristics of a drug product - e.g., tablet, capsule or solution - which contains the drug substance and almost invariably other ingredients, such as excipient, fillers, flavours, preservatives or emulsifiers. The form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder/manufacturer/distributor (e.g. tablets, syrup).
e-Dispensing/ eDispensation	The act of electronically retrieving a prescription and giving the medicine to the patient. Once the medicine has been dispensed, a report on the items dispensed is sent to the prescribing Member State in a structured format.
Electronic Health Record	A comprehensive, structured set of clinical, demographic, environmental and social data information in electronic form, documenting the Health Care given to a single individual. Comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes. A comprehensive, structured set of clinical, demographic, environmental and social data information in electronic form, documenting the Health Care given to a single individual.
Electronic Health Record System	System for recording, retrieving and manipulating information in electronic health records.
European Medicines Agency	A decentralised agency of the European Union (EU). It began operating in 1995. The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.
ePrescription	A medicinal prescription issued and transmitted electronically. The concept of the ePrescription service is understood as the ordering of a prescriptionin software, the electronic transmission of that prescription from the Prescription provider to a Dispense provider, the electronic dispensing of the medicine and the electronic transmission of the dispensed medicine information from the dispenser provider to the prescription provider. The ePrescription service is made up of electronic prescribing and electronic dispensing: ePrescribing is defined as prescribing of medicines in software by a health care professional legally authorized to do so, for dispensing once it has been electronically transmitted, at the pharmacy. eDispensing is defined as the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is dispensed, the dispenser shall report via software the information about the dispensed medicine(s).
General Practitioner	A physician who provides primary care. A general practitioner treats acute and chronic illnesses and provides preventive care and health education for all ages and both sexes.
Generic medicinal product	Shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product had been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives or an active substance shall be considered to be the same active substance, unless they differ significantly in

Concept	Definition
	properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy or the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriated detailed guidelines.
Guideline	A suggested way of compliance when doing something. It is visible to those using or supporting the use of a particular service, but there are no sanctions if it is not followed.
Healthcare	Health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.
Health Professional	A doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment; In some documents, the acronym HCP is used. Doctor of medicine or a nurse responsible for general care or a dental practitioner or amidwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or another professional exercising activities in the healthcare sector whichare restricted to a regulated profession as defined in Article 3(1)(a) of Directive2005/36/EC . This means that a Health Care Professional is a person who delivers health care or care products professionally to any individual in need of health care services, in order to prevent, relieve or treat a medical problem. A Health Care Professional must be related to at least one HCPO.
Hospital Information System	Implemented Solutions in Hospitals for documentation, accounting, etc. HIS delivers PS, eP for eHealth DSI.
Identifier	Non-empty set of attribute values that uniquely characterize an entity in a specific domain of applicability.
Medical (Health) Record	A systematic documentation of a patient's medical history and care. The term 'Medical record' is used both for the physical folder for each individual patient and for the body of information which comprises the total of each patient's health history. Medical records are highly personal documents and there are many ethical and legal issues surrounding them such as the degree of third-party access and appropriate storage and disposal. Although medical records are traditionally compiled and stored by healthcare providers (HP) personal health records maintained by individual patients have become more popular in recent years.
Medication Summary	All prescribed medicine which period of time indicated for the treatment has not yet expired, whether they have been dispensed or not. It is a synonymous of current medication. It contains the following information of each one: active ingredient, strength, posology (number of units per intake, frequency of intakes (per day/month or week) and duration of treatment) and onset date of treatment. At least, a list of current prescriptions with the following information of each one: brand name, active ingredient, pharmaceutical dose form, strength, package size, posology, onset date of treatment and end date of treatment.
Medicinal Prescription	Any medicinal dispensation issued by a professional person qualified to do so.
Medicinal Product	Any substance or combination of substances that may be administered to human beings (or animals) for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions. NOTE 1: A medicinal product may contain one or more manufactured items and one or more pharmaceutical products. NOTE 2: In certain jurisdictions a medicinal product may also be defined as any substance or combination of substances

Concept	Definition
	which may be used to make a medical diagnosis. NOTE 3: Adapted from ENV 13607 and ENV 12610.
Medicinal Product Dictionary	A systematic and accurate listing, description and identification of medicinal products designed to support the use (prescription, dispensing and administration of medications) in clinical care or other purposes (adapted from ISO 19256)
Medicinal Product Package/ Package Type	Delivery unit of a medicinal product in an outer container.
Medicine	(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human or veterinary beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. For UNICOM scope, only medicinal products for human use will be considered.
Member States	In the domain of application of the EU DIR 2011/24, Cross-Border Health, and in particular of Article 14: eHealth, with the term Member States are identified the Central Institutions (Ministries, eHealth Agencies) and the Regional Institution governing the National and Regional Healthcare systems, the Healthcare Provider Organisations and and the ensemble of healthcare services. Member States National Regulatory Competent Authorities (NCA) and EMA marginally falls under the EU DIR 2011/24. In the context of this deliverable, the term “Member States” is used in relation to the Health Care Services, under the domain of application of Article 14. This could be extended or altered by the adoption of the Regulation on the European Health Data Space. When NCA are referred to, explicit reference will be made.
Master Value Sets Catalogue	A collection of terms used within certain parts of the eHDSI pivot documents (either parts describing the patient demographics or the clinical problems for example) based on International Standard code system such as ICD-10, SNOMED CT, ATC classification, EDQM Standard Terms, and UCUM.
Original prescription	The minimum data set defined but as prescribed in the origin country (e.g. the brand name of country A that it will probably be different than the one dispensed in country B).
Patient Summary	An identifiable “data set of essential and understandable health information” that is made available “at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care”; it can also be defined at a high level as: “the minimum set of information need to assure Health Care Coordination and the continuity of care”.
Pharmaceutical Product	Qualitative and quantitative composition of a medicinal product in the dose form approved for administration in line with the regulated product information
Posology	Instruction on number of units per intake, frequency of intakes (per day/month or week) and duration of treatment.
Prescriber	Health Care Professional who issues a prescription.
Prescription	A prescription for a medicinal product or a medical device issued by a member of a regulated health profession within the meaning of Article 3 (1) (a) of Directive 2005/36/EC, who is legally entitled to do so in the Member State in which the prescription is issued.
Route of administration	Indicates the part of the body through or into which, or the way in which, the medicinal product is intended to be introduced. In some cases, a medicinal product can be intended for more than one route and/or method of administration.

Substance	Any matter irrespective of origin which may be: human, e.g. human blood and human blood products; animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts; chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.
System actor	System Actors also known as technical actors include the non-human actors, for instance information system or provides conveying information across borders.
Time valid prescription	It is the time during which the prescription can be dispensed (see Terminology in section 11). E.g. In Andalusia the time validity means that the patient can withdraw the medicine from the pharmacy until the date of the end of treatment while in other countries, like the UK, the patient can withdraw the medicine up to a maximum number of days from the date of issue, e.g. 6 months.
Valid prescription	An "official" prescription, i.e., a prescription made fulfilling the legislation and the procedures defined in that country.

8.2 eHDSI Change Proposal Management Procedure Workflow

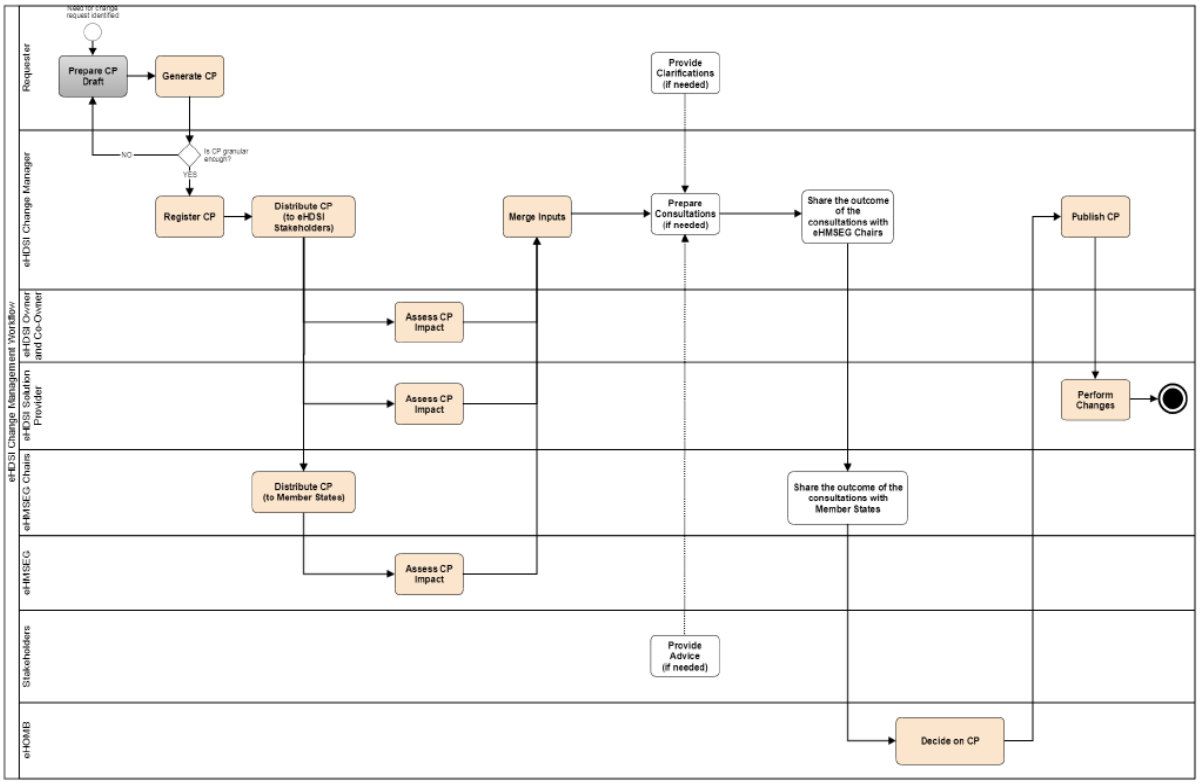

Figure 9: image describing change proposal management procedure workflow.